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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,335	01/17/2007	Federico Ferraresi	8021-97317	5148

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EXAMINER

RANADE, DIVA

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,335	Applicant(s) FERRARESI, FEDERICO	
	Examiner DIVA RANADE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The use of legalese such as 'said' should not be used.

Appropriate correction is required.

Claim Objections

2. The claims 3 and 5 are objected to because they include reference characters which are not enclosed within parentheses.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m). (See Claim 3)

3. Claim 8 is objected to because of the following informalities: Misspelled the word 'said' as 'aid'. Appropriate correction is required.
4. Claims 4-6, 7 and 9 objected to because of the following informalities: Misspelled the word 'characterized' as 'characterised.' Appropriate correction is required.
5. Claim 3 is objected to because of the following informalities: Misspelled the word 'centered' as 'centred.' Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/03196 to Utterberg et al.

a. Claim 1: Utterberg shows an end-of-use protective element (Fig 15-17) for needles for perfusions, transfusions and suchlike which envisages the complete insertion and locking of a needle (not shown) fitted with wings (See page 23 lines 30-35 and Page 24 lines 1-7) within a protective case, characterized by the fact that the said element is composed of a first portion (140) and a second portion (141) which are reciprocally constrained by means of a connecting element (102) at the time of production and shipping and which are capable of being separate at the time of use, said separation capable of being rendered possible by the detachment of the said connecting element, the first and second portions being constrained together, when in use, via locking means (116 and 118) and corresponding slits (between 110 and 112 and between 118 and 120) in the rear part of the said protective element but lacks the fact that the first portion (140) is fitted with a pan (150) and the second portion is fitted with at least two first ridges and at least two second ridges said pan and said first and second ridges being positioned in the respective portions in such a way that they are located on the internal sides of the protective element (100), in a reciprocally opposing position, when the said protective element is in use. Utterberg does not show the pan being located within the first portion however, instead he shows an endcap (150)

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with the same function as the pan which is attachably connected to the first portion. The difference is simply the placement of the element for collection of residual blood. The element is the same. Therefore, modifying the position of the endcap of Utterberg to the position of the pan would have been obvious to one skilled in the art during the time of the invention in order to avoid the need for extra elements and in order to permit ease of use. Next, he does not show two sets of ridges as mentioned above but does show one set of ridges (130 and 132) and shows notches 107 on one side and 108 on the other which are all positioned in such a way that they are located on the internal sides of the protective element. These elements are performing the same function as ridges 24 and 20 in the invention. Ridges (130 and 132) delimit the lateral movement of the needle like 20 of the invention, while notches (107 and 108) are used to maintain a flattened position of the wings like 24 of the invention. Therefore, it would be obvious to one skilled in the art during the time of the invention modify the elements in terms of positioning and shape in order to increase the efficacy of delimiting the lateral movement and maintaining the placement of the wings and also to increase the ease of manufacturing the apparatus by including all functioning elements on one side. Furthermore, the notches (107 and 108) are cut into the protective elements leaving ridges (Not numbered See Fig 15) as a result.

b. Claim 2: Utterberg shows a protective element characterized by the fact that that first portion (140), the second portion (141) and the connecting element

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(102) are created by a moulding process in a single operation (See Page 23 lines 30-31 and lines 14-18).

c. Claim 3: Utterberg shows a container for the drops of residual blood that may leak from needle after its use and its retraction into the said protective element centered with the longitudinal central axis of the first portion in its extended configuration (See Fig 15 Endcap #150 is snapped on after use to prevent blood from escaping) but lacks, a pan corresponding to the longitudinal central axis of the first portion in its use configuration; the pan being designed to act as a container. The difference is simply the placement of the element for residual blood. Therefore, modifying the position of the endcap of Utterberg to the position of the pan would have been obvious to one skilled in the art during the time of the invention in order to avoid the need for extra elements and in order to permit ease of use.

d. Claim 4: Utterberg does not show that a frontal protrusion is positioned in front of the pan facing the front part (103); said protrusion being designed to constitute both a shoulder for the point of the needle and a further barrier against blood leaking from the protective element (100), in the area corresponding with its front part. However, given the modification shown above for claim 3, if the placement of the placement of the endcap is changed to reduce the number of extra elements than the addition of frontal protrusions which would be capable of acting as a further barrier against blood leaking from the protective element could be included similar to ridges (103 and 132). Therefore, upon modifying the

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position of the endcap of Utterberg with the position of the pan it would have been obvious to one skilled in the art during the time of the invention to include frontal protrusions like (130 and 132) in order to act as a further barrier against blood leaking.

e. Claim 5: Utterberg shows that the height of the first ridges (130 and 132) is equal to the distance, when the protective element (100) is in use, between the lower surface of the second portion (141) and the steps (131 and 133 reference uses the term notches to describe the element, however, if it is a notch it contains 2 steps on either side of the notch) on the first portion (140); said height being designed to permit, when the protective element (100) is in use, the co-operation being designed to prevent blood leaking from the protective element (100) in the area corresponding with the external edges (101) of the said protective element.

f. Claim 6: Utterberg does not show the distance between the second notches (107 and 108) corresponding with the distance between the steps (131 and 133) but the notches 107 and 108 run through the protective element from end to end when in use in order to maintain the position of the wings. Therefore, it would be obvious to one skilled in the art during the time of the invention that the distance between the ends of 107 and 108 correspond with the distance between steps 131 and 133 since 107 and 108 or 131 and 133 are parallel to each other and on two separate ends when the protective element is in use.

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g. Claim 7: Utterberg shows a base surface (Not numbered), designed to remain inside the said protective element when the latter is in use, there is a groove created (Described on Page 24 lines 8-10) which extends, essentially, along the entire length of the first portion (140).

h. Claim 8: Utterberg shows that the height internal of the second notches (107 and 108) is equal to the distance that exists, when the protective element (100) is in use between the top surface of the notch and the lower surface of the notch (See Fig 15 107 and 108) minus the thickness of the wings (Described on Page 23 lines 15-30); said height being designed to permit, when the protective element (100) is in use, cooperation between the said second notches with the upper surface of the said wings; the said cooperation being designed to constitute a further protective element against the possibility of blood leaking out from the protective element (100) laterally in the area in corresponding with the groove (Described on Page 24 lines 8-10). However, Utterberg lacks when the protective element is in use the height is measured as the distance between the lower surface of the second portion (141) and the base surface (Not Shown) of the said protective element minus the thickness of the wings. But, since the purpose of the notches is to keep the wings in place when the protective element is in use, to would be obvious to one skilled in the art that if the notches were on the same side this measurement could take. Therefore, it would be obvious to one skilled in the art during the time of the invention to manufacture the protective element with notches on one side in order to manufacture the

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apparatus with more ease and create one less measurement when fitting the wing in place. Furthermore as stated above. If the notches have been cut as to remove material to create space for the wing a ridge will also result (Not number see Fig 15).

i. Claim 9: Utterberg shows that each step (131 and 133) separates the base surface (Not numbered see Fig 15) from the groove (Not numbered see Fig 15) on both sides of the central longitudinal axis of the first portion (140).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on (571) 272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. R./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763